THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 22

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte DORON FRIEDMAN, JOSEPH SCHWARTZ and HAIM AVIV

Appeal No. 95-4914
Application No. 08/036,116[1]

HEARD: April 7, 1999

Before KIMLIN, JOHN D. SMITH, and GARRIS, Administrative Patent Judges.

JOHN D. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal pursuant to 35 U.S.C. § 134 from the final rejection of claims 1-31 and 35. Representative claims 1, 3, 5, 6, and 35 are reproduced below:

1. A composition for topical application of pharmaceuticals or cosmetics comprising submicron size droplets comprising

[1] Application for patent filed March 23, 1993.

about 0.5 to 30% of a first component of an oily liquid, about 0.1 to 10% of a second component of an emulsifier and about 0.05 to 5% of a surfactant, said droplets having a mean droplet size in the range of 0.05 to 0.5 μm, wherein said composition provides an enhanced topical and/or transdermal systemic effect compared to the same compositions which have larger size droplets.

3. The composition of claim 1 wherein the first component comprises a medium chain triglyceride oil comprises a chain length of 8 to 12 carbons, a vegetable oil, a mineral oil, an oil of animal source, a synthetic derivative thereof, or mixtures thereof.

5. The composition of claim 1 wherein the emulsifier is a phospholipid compound or a mixture of phospholipids.

6. The composition of claim 5 wherein the phospholipid is lecithin, phosphatidylcholine, phosphatidylethanolamine or mixtures thereof.

35. A composition for enhanced topical and/or transdermal delivery of pharmaceuticals comprising submicron droplets having a mean droplet size of 0.05 to 0.3 microns dispersed in an aqueous medium containing one or more pharmaceutically-acceptable surfactants, wherein said droplets are comprised of an effective amount of a water-insoluble drug mixed with one or more medium chain triglyceride oils having a chain length of eight to twelve carbons.

The references of record relied upon by the examiner are:

de Vringer	EPA 0506197	Sep. 30, 1992
Snyder	EPA 0014509	Aug. 20, 1980

The following rejections are before us:

1) claims 1-16, 23-27, 29, and 30 under 35 U.S.C. § 103 as unpatentable over de Vringer;

2) claims 17-21 under 35 U.S.C. § 103 as unpatentable over de Vringer in view of Snyder.

3) all appealed claims under the first paragraph of 35 U.S.C. § 112, "written description requirement";

4) claims 3 and 30 under the first paragraph of 35 U.S.C. § 112, "enablement requirement"; and

5) claims 3 and 22[2] under the second paragraph of 35 U.S.C. § 112 as indefinite.

THE SUBJECT MATTER ON APPEAL

The subject matter on appeal is directed to a composition for topical application of either pharmaceuticals or cosmetics which comprises submicron size droplets having a mean droplet size in the range of 0.05 to 0.5 microns (50 to 500 nanometers). The droplets are comprised of three basic components[3]; about 0.5 to 30% of an oily liquid, about 0.1 to

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[2] Rather than claim 22, the examiner inadvertently refers to claim 33 in his answer.

[3] The relative proportion ranges for the three components are apparently expressed as weight percents of each component based on the total weight of an emulsion containing the droplets. See the specification at page 13, lines 14-16. However, compare the specification at page 3, lines 15-20.

10% of an emulsifier, and about 0.05 to 5% of a surfactant. The composition may also include an active ingredient[4]. The composition provides an enhanced topical and/or transdermal systemic effect compared to compositions having larger droplets.

THE PRIOR ART REJECTIONS

Appealed claims 1-16, 23-27, 29, and 30 stand rejected under 35 U.S.C. § 103 as unpatentable over de Vringer. Appealed claims 17-21 stand similarly rejected under the same section of the statute as unpatentable over de Vringer in view of Snyder[5]. We sustain the prior art rejections of the claims so rejected.

Appellants contend that de Vringer (published September 30, 1992) is not prior art to the present application, because appellants are allegedly entitled to the benefit of the filing date of a previously regularly filed application for the same invention in Israel (Israeli application 101,387 filed March 26, 1992) pursuant to 35 U.S.C. § 119. However, as noted by

[4] See claims 11-14, 22-24, and 26-28.

[5] Appealed claims 22, 28, 31, and 35 were not rejected on any prior art basis.

the examiner, when the effective filing date for subject matter claimed in a U.S. application is in issue, the foreign application relied upon for priority under the above section of the statute must be examined to determine, inter alia, whether it describes within the meaning of 35 U.S.C. § 112's first paragraph, what is claimed in the U.S. application. In re Gosteli, 872 F.2d 1008, 1011, 10 USPQ2d 1614, 1616 (Fed. Cir. 1989). Here, we agree with the examiner that the foreign priority document in question does not describe (35 U.S.C. § 112, first paragraph) what is now being claimed in the present application.

Appealed claim 1 requires, inter alia, a droplet comprising "about 0.1 to 10% of a second component of an emulsifier", and appealed claim 5 specifies that the emulsifier is a phospholipid compound or a mixture of phospholids. Even were we to agree that the disclosure in the Israeli application at page 4, lines 11-14 describes a droplet comprised of first, second and third components as in the present application, no descriptive support is present in the Israeli application regarding the claimed relative proportion ranges for the respective first, second, and third components.

Accordingly, we agree with the examiner that Israeli application does not reasonably convey to the artisan a description of a droplet comprising "about 0.1 to 10% of a second component of an emulsifier", as set forth in appealed claim 1. See the answer at page 11. We also agree with the examiner that the exemplification of lecithin[6] as a dispersant in a composition described in the Israeli application does not reasonably convey to the artisan a description of the more comprehensive subgenus of phospholipid compound emulsifiers recited in appealed claim 5. We further agree with the examiner that the Israeli application contains no description of a "physiologically acceptable inorganic thickening agent" component as required by appealed claim 18. Therefore, except for appealed claim 35, which was not rejected under 35 U.S.C. § 103, de Vringer is competent prior art against the appealed claims so rejected.

Recognizing that de Vringer's disclosures are highly relevant to the subject matter defined by the rejected claims

[6] Lecithins are phosopholipids which are mixtures of diglycerides of fatty acids linked to the choline ester of phosphoric acid.

on appeal, appellants argue that de Vringer is distinguished from the appealed claims on the basis of the "oily liquid" component requirement as contrasted to de Vringer who teaches the use of solid lipid particles. Appellants provide no limiting definition in their specification requiring the claimed oily liquid component to be a liquid at any particular temperature, however, while de Vringer indicates that his "solid lipoid nanoparticles" are "solid at room temperature". See de Vringer at page 3, lines 40. The examiner points out that, like appellants' claimed oily liquid component, which may be a "medium chain triglyceride oil" having "a chain length of 8 to 12 carbons" (appealed claim 3), de Vringer also discloses triglycerides having 10-30 carbon atoms, such as glyceryl trilaurate (a 12 carbon chain length triglyceride) as well as hydrogenated castor oil" as "solid lipid" materials useful in his compositions. See de Vringer at page 3, lines 54-55. Thus the record supports the examiner's contention that some claimed "overlap" exists between the appellants' oily liquid component and the "solid lipoids" of de Vringer. Moreover, de Vringer also contemplates the addition of "liquid or semisolid lipids" which are mixed with the solid lipoid

nanoparticles. See de Vringer at page 5, lines 13-21. Accordingly, we agree with the examiner that a prima facie case of obviousness is established for the subject matter defined by the broader claims on appeal.

We also find that de Vringer fairly suggests the subject matter of the separately argued dependent claims. For example, appealed claim 2 specifies a mean droplet size range of between about 0.1 and 0.3 microns (i.e., between 100 and 300 nanometers) while de Vringer discloses a somewhat broader droplet size range between 50 and 1000 nanometers(page 4, line 35) and exemplifies a composition having a mean particle size droplet of 132 nanometers (page 6, line 12). With respect to the appealed claims 20 and 21, which call for a skin penetration enhancer component, we note that de Vringer also contemplates the use of penetration enhancers. See page 5, lines 25 and 26 of the reference. With respect to appellants' arguments that imply that de Vringer does not suggest application of the prior art compositions to treat skin disorders, for example, as specified in appealed claim 25, we point out that de Vringer's compositions are useful as anti-psoriatics and anti-eczema agents. See the reference at page

5, line 7. Finally, appellants make no argument that the examiner has improperly combined the disclosures of Snyder with de Vringer to suggest the use of a thickening agent in de Vringer's compositions.

To the extent that appellants have argued that the use of the claimed submicron size droplets provide for unexpected results in terms of "an enhanced topical and/or transdermal systemic effect" (appealed claim 1), suffice it to say that appellants refer to no comparisons with de Vringer's submicron size droplet compositions, i.e., the closest prior art. In light of the above, we affirm the rejections of appealed claims 1-21, 23-27, 29, and 30 under 35 U.S.C. § 103.

Pursuant to 37 C.F.R. § 1.196(b), we extend the prior art rejection to appealed claim 28 under 35 U.S.C. § 103 as obvious over de Vringer. This claim calls for a retinoid as an active ingredient. At page 5, line 3, de Vringer likewise suggests that retinoids may be combined in the compositions as a topically effective ingredient.

THE 35 U.S.C. § 112, FIRST PARAGRAPH, DESCRIPTION REQUIREMENT REJECTION

All appealed claims stand rejected under 35 U.S.C. § 112, first paragraph, written description requirement, on the grounds that the specification as originally filed only describes the surfactant component of the oil droplets as a non-ionic surfactant, and thus does not reasonably convey to the skilled artisan that the applicants had possession of the broader genus now claimed, i.e., "surfactants". We agree with appellants that the disclosure in the specification at page 9, lines 17-21 provides reasonable descriptive support for the now more broadly claimed "surfactant" component. We also agree with appellants that the language in appealed claim 3 that a medium chain length triglyceride oil "comprises a chain length of 8 to 12 carbons" is supported by the specification at page 3, lines 25-30. We, therefore, reverse the "written description" rejections of the appealed claims.

THE 35 U.S.C. § 112, FIRST PARAGRAPH, ENABLEMENT REJECTIONS

Appealed claims 3 and 30 also stand rejected under 35 U.S.C. § 112, first paragraph, "enablement requirement". See the answer at page 6. We reverse these rejections essentially for the reasons set forth in the brief at pages 8-11.

Basically, we agree with appellants that the examiner has failed to meet his burden of establishing that undue experimentation would be required on the part of one skilled in this art to prepare compositions as claimed which are useful for the asserted utility (appealed claim 30).

THE 35 U.S.C. § 112, SECOND PARAGRAPH REJECTIONS

Appealed claims 3 and 33[7] stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite for several reasons. See the answer at page 4 and 5. We also reverse these rejections essentially for the reasons in the brief at pages 11 and 12.

SUMMARY

The examiner's decision refusing to allow claims 1-21, 23-27, 29, and 30 is affirmed. The examiner's decision refusing to allow claims 22, 28, 31, and 35 is reversed. A new rejection has been imposed against claim 28.

In addition to affirming the examiner's rejection of one or more claims, this decision contains a new ground of

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[7] The examiner apparently intended to reject claim 22 instead of claim 33, since claim 22 refers to a "lipophilic peptide". See footnote 2. We note that appellants' arguments are directed in relevant part to claim 22.

rejection pursuant to 37 CFR § 1.196(b) (amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)). 37 CFR § 1.196(b) provides that "[a] new ground of rejection shall not be considered final for purposes of judicial review."

Regarding any affirmed rejection, 37 CFR § 1.197(b) provides:

> (b) Appellant may file a single request for rehearing within to months from the date of the original decision . . . .

37 CFR § 1.196(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (37 CFR § 1.197(c)) as to the rejected claims:

> (1) Submit an appropriate amendment of the claims so rejected or a showing of a facts relating to the claims so rejected, or both, and have the matter considered by the examiner, in which event the application will be remanded to the examiner. . . .

> (2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeal and Interferences upon the same record. . . .

Should the appellant elect to prosecute further before the Primary Examiner pursuant to 37 CFR § 1.196(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If the appellant elects prosecution before the examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for rehearing thereof.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART/196 (b)

EDWARD C. KIMLIN Administrative Patent Judge	)	
JOHN D. SMITH Administrative Patent Judge	)	BOARD OF PATENT APPEALS AND INTERFERENCES
BRADLEY R. GARRIS Administrative Patent Judge	)	

lp

Appeal No. 95-4914
Application No. 08/036,116

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Appeal No. 95-4914
Application No. 08/036,116

APJ JOHN D. SMITH

APJ KIMLIN

APJ GARRIS

DECISION: AFFIRMED-IN-PART
Send Reference(s): Yes No
or Translation (s)
Panel Change: Yes No
Index Sheet-2901 Rejection(s): _____

Prepared: January 27, 2000

Draft Final

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OB/HD GAU

PALM / ACTS 2 / BOOK
DISK (FOIA) / REPORT